DETAILED ACTION

Applicant's amendment filed 4-14-11 has been entered. Claims 1, 2, 5, 6, 9, 13, 45, 49 and 50 have been amended. Claims 31 and 67 have been canceled. Claims 1-11, 13, 17, 19-30, 45-52, 54-66, 69 and 70 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11, 13, 17, 19-30, 45-52, 54-66, 69 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendment filed 4-14-11 necessitates this new ground of rejection.

The phrase "pluripotent adult stem cells" in amended claims 1 and 45 is vague and renders the claim indefinite. It is unclear as to the metes and bounds of what would be considered "pluripotent adult stem cells". The specification fails to provide specific definition for "pluripotent adult stem cells". It was well known in the art that adult stem cells are "multipotent" stem cells, for example, hematopoietic stem cells, mesenchymal stem cells, neural stem cells, and follicular stem cells. It is unclear what kind of cells is considered "pluripotent adult stem cells". Claims 2-11, 13, 17, 19-30 and 69 depend from claim 1 but fail to clarify the indefiniteness. Claims 46-52, 54-66 and 70 depend from claim 45 but fail to clarify the indefiniteness.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-11, 13, 17, 19-30, 45-52, 54-66, 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment filed 4-14-11 necessitates this new ground of rejection.

The phrase "pluripotent adult stem cells" in amended claims 1 and 45 is considered new matter. Applicant points out support for such amendment on page 12, lines 6-8, of the specification, however, the specification only states "adult stem cells" rather than "pluripotent adult stem cells". There is no support for the phrase "pluripotent adult stem cells" in the specification. Thus, the phrase set forth above is considered new matter. Claims 2-11, 13, 17, 19-30 and 69 depend from claim 1. Claims 46-52, 54-66 and 70 depend from claim 45.

5. Claims 1-11, 13, 17, 19-31, 45-52, 54-67, 69 and 70 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing embryoid bodies (EBs) from pluripotent embryonic stem (ES) cells, embryonic germ (EG) cells or pluripotent non-embryonic stem cells, does not reasonably provide enablement for a method for producing embyroid bodies (EBs) from multipotent cells, including early primitive ectoderm-like cells, multipotent adult progenitor cells, adult neural stem cells, adult mesenchymal stem

cells, ductal stem cells, muscle derived stem cells, hematopoietic stem cells, pancreatic stem cells, follicular stem cells, and any other type of adult stem cells or progenitor cells, and the production of a differentiated cell which is a cardiomyocyte from said EBs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 2-7-11. Applicant's arguments filed 4-14-11 have been fully considered but they are not persuasive.

Applicant argues that even assuming that the lack of reported EBs formation by a cell is evidence of the cell's inability to form EB, the specification is still enabling because the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim not enabled. Using the teachings applicable to pluripotent stem cells, one skilled in the art can determine whether a particular embodiment is operative or inoperative within expenditure of no more effort than is normally required in the art 9amendment, p. 8-9). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-7-11.

As discussed above, the specification fails to specifically define the phrase "pluripotent adult stem cells". The phrase "pluripotent adult stem cells" can encompass early primitive ectoderm-like cells, multipotent adult progenitor cells, adult neural stem cells, adult mesenchymal stem cells, ductal stem cells, muscle derived stem cells, hematopoietic stem cells, pancreatic stem cells, follicular stem cells, and any other type of adult stem cells or progenitor cells. The specification fails to provide adequate guidance and evidence for how to produce EBs from numerous different pluripotent adult stem cells with the final concentrations of 500 EBs/ml or 100-2000 EBs/10ml.

A search of the state of the art of generating EBs, it is apparent that only pluripotent embryonic stem cells or embryonic germ cells can produce EBs under a certain culturing condition. There is no evidence of record that demonstrate the formation of EBs from various pluripotent adult stem cells in vitro or in vivo. Although the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim not enabled, however, the specification must provide sufficient enabling disclosure for the full scope of the invention claimed. One skilled in the art can determine whether a particular embodiment is operative or inoperative but it does not make the full scope of the invention enabled. The specification only provides enabling disclosure for a small portion of the full scope of the claimed invention. The specification fails to provide adequate guidance and evidence for how to produce EBs from numerous different pluripotent adult stem cells. Absent specific guidance, one skilled in the art at the time of the invention would not know how to form EBs from numerous different pluripotent adult stem cells in vitro or in vivo and would require undue experimentation to practice over the full scope of the invention claimed.

Conclusion

No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Shin-Lin Chen/
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